

**REMARKS**

This response is submitted to address the issue of non-compliance under 37 C.F.R. 1.121(b) raised by the previously submitted response. This submission replaces in its entirety the previously submitted Amendment In Response To Non-Final Office Action, filed October 2, 2006.

Claims 1-64 are pending in this application. Claims 1-26, 34, 37 and 41-64 are withdrawn pursuant to a restriction requirement. Claim 27 is amended herein. Support for amended claim 27 can be found in the specification at, for example, paragraphs [0010], [0018] and [0020] and in the claims as filed. Claims 32-33 and 35 are canceled. New claim 65 is added, which falls within the scope of Invention II, as described on page 2 of the Office Action. Support for new claim 65 can be found in the specification at, for example, paragraph [0023] and in the claims as filed.

No new matter has been added by way of these amendments. Applicants respectfully request entry of the claim amendments and reconsideration in view of the following remarks.

**Restriction Requirement under 35 U.S.C. 121**

Applicants affirm the election of Invention II (claims 27-40) and species 2(b) (claim 38), without traverse. Claims 1-26 and 41-64 are withdrawn as being drawn to non-elected inventions. Claims 1-26 are withdrawn from further consideration as being drawn to non-elected species.

Applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

**Objection to the Specification**

Upon further analysis, applicants find no basis to amend the specification. It is our understanding that the MPEP expressly forbids amending the specification in this manner, as it would constitute new matter. Further, the MPEP provides no basis to require applicants to amend the specification for indefiniteness, which goes to the claims. Applicants respectfully submit that

the specification in its entirety is clear as filed. Accordingly, applicants respectfully request that the objections to the specification be withdrawn.

Objection Under 37 CFR 1.75(c)

Claims 32-33 are objected to under 37 CFR 1.75(c) as being in improper dependent form. Claims 32-33 are canceled herein, rendering the objections moot. Accordingly, Applicants respectfully request that the objection under 37 CFR 1.75(c) be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 27-33, 35-36 and 38-40 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner has alleged that claim 27 omits essential steps, is unclear and lacks antecedent basis. Further, the Examiner has alleged that claims 32-33 and 35 lack antecedent basis and/or are unclear. Applicants respectfully traverse the rejection.

Solely to advance prosecution, claim 27 is amended herein to address issues raised by the Examiner. Support for claim 27 is found in the specification, at, for example, paragraphs [0010], [0018] and [0020] and in the claims as filed. Claims 32-33 and 35 are canceled herein, rendering the rejections moot.

In view of the claim amendments, applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 27-28, 30-33, 35-36 and 39-40 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Conti-Fine (U.S. 6,759,385). Applicants respectfully traverse the rejection.

“To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 U.S.P.Q.2D (BNA) 1375, 1376 (Fed. Cir. 2001). Anticipation is avoided if any element of the claim is not disclosed in the cited reference. MPEP § 2131.

The Office alleges that Conti-Fine (hereinafter ‘385) at column 6, lines 61-63 describes a method for determining a therapeutic protocol for a subject afflicted with an auto antibody specific for a natural substance. *See* Office Action at page 11. Applicants respectfully disagree. The portion of ‘385 cited by the Office refers to “a method to inhibit or suppress an antibody-mediated disease,” not a method of guiding therapeutic decisions, as claimed. *See* ‘385 at column 6, lines 61-63.

The Office further cites ‘385 at column 5, line 67; column 23, lines 30-31 and 35-36; column 24, lines 21-23; and column 7, lines 43-48 as allegedly providing the elements of claim 27. Respectfully, the portions of the ‘385 patent cited by the Office are unrelated to one another and to the invention as claimed. Citation of disparate portions of the reference does not satisfy the requirement that the elements be arranged as in the claim. For example, the “samples” described at column 5, line 67, relate to a method to identify an immunodominant epitope sequence, while column 23, lines 30-31 and 35-36, relates to identifying an antigen and determining its amino acid sequence. Column 24, lines 21-23, describes a method for determining tolerogenic efficacy of peptide epitopes. Finally, column 7, lines 43-48, refers to a therapeutic method, comprising nasally administering a protein and an epitope peptide in an amount effective to suppress an immune response to the exogenously introduced protein. *See* ‘385 at column 7, lines 40-48.

The ‘385 patent does not disclose each and every element of the claimed invention, and thus does not anticipate the claims. Specifically, the ‘385 patent does not disclose: obtaining a sample from a subject; assessing the sample for the presence of an auto antibody specific for a natural substance, wherein the auto antibody is produced as a result of therapeutic administration of the natural substance. Further, ‘385 fails to disclose basing therapeutic decisions to initiate, terminate or adjust the level of administration of the natural substance on the presence of such an auto antibody.

The Office asserts that '385 anticipates claim 31 by describing a sandwich assay. *See* '385 at column 24, line 7. The ELISA assay referred to in '385 is utilized to analyze cytokine secretion after administration of an epitope peptide, and does not involve the assessment of auto antibodies, as claimed. Thus, the cited portion of '385 does not anticipate claim 31.

Finally, with respect to claims 39-40, the Office asserts that the '385 patent describes natural substances bound by low molecular weight labels. *See* Office Action at page 12, citing '385 at column 23, lines 30-31, 35-36 and 10. Respectfully, column 23, lines 30-31 and 35-36 relate to the identification of an antigen and determination of its amino acid sequence. Claims 39-40 require assessing the presence of an auto antibody, and are thus not anticipated by the cited portion of '385. Moreover, the "Fpitope" [sic] peptide referred to in the section heading at column 23, line 10, does not appear to constitute a "natural substance bound by a low molecular weight label" as required by the claims.

Because the '385 patent fails to disclose each and every limitation of the claimed invention, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

#### Rejection Under 35 U.S.C. § 103

Claims 29 and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Conti-Fine (U.S. 6,759,385) in view of Bunn, 346 N. ENGL. J. MED. 522 (2002). The Office alleges that '385 describes a method for determining a therapeutic protocol as claimed, and that Bunn describes a method of deciding to initiate or terminate administration of erythropoietin, and thus it would have been obvious to one of skill in the art to apply the method of '385 to erythropoietin. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a

reasonable expectation of success found in the prior art. Third, the prior art reference must teach or suggest all the claim limitations. *See In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2143.

As discussed in detail above, the '385 patent does not teach or suggest all the limitations of the claimed invention, and thus does not provide a method of guiding therapeutic decisions, as claimed. This deficiency is not remedied by combination with Bunn.

Bunn describes a rare but serious side effect in a small group of renal failure patients treated with epoetin, who developed red-cell aplasia and severe anemia because of a drug-induced autoimmune response. *See* Bunn, page 522, left column, paragraph 3. This disclosure alone is insufficient to render the claimed invention obvious. The Office must still provide a motivation to combine Bunn with the '385 patent, as well as a reason to believe that such a combination would be successful.

The Examiner appears to suggest that a motivation to combine can be found in Bunn's statement that "about 3 million patients worldwide were being treated with epoetin," as well as his statement that "[t]he clinical picture of rapidly developing transfusion-dependent anemia is so dramatic that such cases are unlikely to escape attention." *See* Office Action at page 13-14, quoting Bunn at page 522-23. Applicants respectfully suggest that, read in context, the cited portions of Bunn do not support this contention. Bunn points out that "[g]iven that about 3 million patients worldwide are being treated with epoetin, *the incidence of drug-induced erythroid aplasia is remarkably low.*" *See* Bunn, page 522 (emphasis added). Further, because of the dramatic nature of such adverse events, they are "unlikely to escape attention" by treating physicians. These statements do not provide a motivation to combine the cited references. Further, based on the disclosure of '385, one of skill in the art would not have had a reasonable expectation of success that the combination of references would lead to the invention as claimed.

Accordingly, applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

In view of the above discussion, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952 referencing docket No. 532212002000**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By   
Leslie A. Robinson

Registration No.: 54,403  
MORRISON & FOERSTER LLP  
12531 High Bluff Drive, Suite 100  
San Diego, California 92130-2040  
(858) 314-7692